REMARKS

Amendments to the Claims

Claims 1 and 15 are amended to delete recitation of "immunogenic." Conforming amendments are made to dependent claims.

Claim 15 is amended to recite that the OmpA and PPIase proteins are substantially pure. Support is throughout the specification, for example, at page 6, lines 29-31, page 8, lines 6-8, and page 15, lines 1-5.

Clarifying amendments are made to claims 2-7. No new matter is added.

Rejection of Claims 1, 2, 4, and 15-18 Under 35 U.S.C. § 112, first paragraph

Claims 1, 2, 4, and 15-18 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description.

To advance prosecution, Applicants have deleted the "immunogenic" language from the claims. Amended claims 1 and 15 are adequately described as explained in Example 11 of the Written Description Training Materials (Rev.1, March 25, 2008). Claim 1 of Example 11 recites an isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO:2. The manual teaches that the skilled artisan would have been in possession of the genus of nucleic acids of the claim: "[W]ith the aid of a computer, one could list all of the nucleic acid sequences that encode a polypeptide with at least 85% sequence identity to SEQ ID NO:2." *Id.* at page 41. Example 11's fact pattern is directly analogous to the pending claims. Here, the skilled artisan would have possession of each protein that has 70% or more identity to the SEQ

ID NOS recited in claim 1 because the artisan could use a computer to identify all the relevant protein sequences.

Independent claims 1 and 15 are adequately described. Claims 2, 3, and 16-19 depend from claims 1 or 15 and are adequately described for the same reason. Please withdraw the rejection.

Rejection of Claims 15-19 Under 35 U.S.C. § 101

Claims 15-19 are rejected under 35 U.S.C. § 101 as directed to non-statutory subject matter. To advance prosecution, claim 15 is amended to recite that the OmpA and PPIase proteins are substantially pure in accordance with Examiner Devi's suggestion. Applicants thank Examiner Devi for the suggestion. Claims 16-19 depend from claim 15 and are also directed to statutory subject matter. Please withdraw the rejection.

Rejection of Claims 2 and 4 Under 35 U.S.C. § 112, Second Paragraph

Claims 2 and 4 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly lacking antecedent basis for the limitations comprising "an OmpA" and "a PPIase" protein respectively. Claims 2 and 4 are amended to recite "the OmpA" and "the PPIase," respectively, to supply antecedent basis. Please withdraw the rejection.

Rejection Under 35 U.S.C. § 102(b)

Claims 1, 2, 4, and 15-19 are rejected stand rejected under 35 U.S.C. § 102(b) as anticipated by Fontana (WO 02/079243).

The Patent Office contends that the claims are anticipated because the proteins antigens taught by Fontana are substantially pure. The Patent Office further contends that the open claim language comprising "does not exclude any number of additional unrecited proteins even in major amounts" and that "[w]hen the two specific polypeptide species are taught, the claims are anticipated no matter how many other polypeptide species are additionally named." Office Action at page 16.

Applicants respectfully traverse the rejection.

An anticipating reference "must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements 'arranged as in the claim.'" *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)); *see also In re Arkley*, 455 F.2d 586, 587(C.C.P.A. 1972) ("[The] reference must clearly and unequivocally disclose the claimed [invention] or direct those skilled in the art to the [invention] without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference."); see also *In re Ruschig,* 379 F.2d 990 (C.C.P.A. 1967).

Fontana does not anticipate claim 1 or claim 15 because there is no teaching to arrive at a composition comprising both an OmpA protein and a PPIase protein. Fontana provides a laundry list of 4311 proteins—which may anticipate a claim directed to any of the individual species of polypeptides—but there is no guidance whatsoever in Fontana to select two particular proteins and combine them in a composition, let alone select OmpA and PPIase, the elected combination.

In fact, the odds of a skilled artisan arriving at the combination of OmpA and

PPIase from a list of 4311 proteins without any guidance is 1 in over 18 million.[1] Here, as in *In re Ruschig*, "one is left to selection from the myriads of possibilities encompassed by the broad disclosure, with no guide indicating or directing that this particular selection should be made rather than any of the others which could also be made." 379 F.2d at 995.

In contrast to Fontana's absence of information about the functional importance of the elected combination of OmpA and PPIase, Applicants specification teaches that each protein is particularly important to bacterial adhesion and cell entry. Mutant bacteria lacking PPIase "showed a 30-fold reduction in adhesion and a similar reduction in invasion." Specification at page 16, lines 7-9. Similar results were obtained with mutant bacteria lacking OmpA: "Wild type F62 [bacteria] bound to significant numbers on the cell monolayers and some bacteria were observed inside the cells (white arrows; Figure 20A). In contrast, very few ΔOmpA bacteria either bound to or entered the cells. (Figure 20B)." Specification at page 18, lines 27-30. Applicants' specification therefore demonstrates that both proteins are functionally important for bacterial infection and thus antibodies against these proteins would be useful for inhibiting infection.

Because Fontana does not teach the recited elements "arranged as in the claim" as required in *Net MoneyIN, Inc.*, and because Fontana has no blazemarks to guide selection as required in *In re Ruschig*, it does not anticipate claims 1 or 15. Claims 2, 4, and 16-19 depend from claim 1 or 15 and are not anticipated either.

Applicants request that the Patent Office reconsider and withdraw the rejection.

[1] Picking OmpA from a list of 4311 and PPIase from the resulting list of 4310 gives 18,580,410 possible combinations (4311 X 4310).

Rejection of Claims 15-19 Under 35 U.S.C. § 102(b)

Claims 15-19 stand rejected under 35 U.S.C. § 102(b) as anticipated by Carson.[2] The Office Action contends that because the claims do not recite isolated and/or purified antigens, they read on whole cells of *Neisseria gonorrhoeae*. Office Action at pages 21-22.

To advance prosecution, independent claim 15 is amended to recite that the OmpA and PPIase proteins are substantially pure. Carson does not teach substantially pure OmpA or PPIase proteins. Please withdraw the rejection.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Dated: December 10, 2010

By: /Fraser D. Brown/
Fraser D. Brown
Registration No. L0617

Customer No. 22907

[2] Carson *et al.*, "Ferric enterobactin binding and utilization by *Neisseria gonorrhoeae*," J Bacteriol. 1999 May;181(9):2895-901.